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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,158	04/12/2005	Hee-Sup Shin	7037-70886-01	7490
24197	7590	10/24/2006	EXAMINER	
KLARQUIST SPARKMAN, LLP 121 SW SALMON STREET SUITE 1600 PORTLAND, OR 97204			CHERNYSHEV, OLGA N	
			ART UNIT	PAPER NUMBER
			1649	

DATE MAILED: 10/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/531,158	Applicant(s) SHIN ET AL.	
	Examiner Olga N. Chernyshev	Art Unit 1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 11 is/are pending in the application.
- 4a) Of the above claim(s) 5-9 and 11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 April 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/12/5</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I in the reply filed on August 21, 2006 is acknowledged. The traversal is on the ground(s) that claim 1, as amended, reflects on the special technical feature, which is treating depression by administration of a N-type calcium channel inhibitor. This is not found persuasive because methods of administration of a N-type calcium channel inhibitors are disclosed in the art, therefore, this alone cannot represent a special technical feature, as a contribution over prior art. Further, because the instant specification fails to teach how to treat depression by administration of a N-type calcium channel inhibitors, as fully explained in section 3 of the instant office action, it is maintained that the first recited claim does not read on a unifying special technical feature.

The requirement is still deemed proper and is therefore made FINAL.

Claims 5-9 and 11 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on August 21, 2006.

Claims 1-4 are under examination in the instant office action.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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3. Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1-4 are directed to methods for treating depression in a subject by administration of a N-type calcium channel inhibitor. However, the instant specification fails to provide enough guidance for one skilled in the art on how to practice the instant methods, thereby requiring undue experimentation to discover how to use Applicant's invention, as currently claimed.

The factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and, (8) the breadth of the claims. *In re Wands*, 8 USPQ2d, 1400 (CAFC 1988).

The nature of the invention is the demonstration that transgenic mice, which lack 1B N-type calcium channel gene (1B knockout mutant), performed differently during a forced swimming test and a tail suspension test (pp. 6-7, and Fig. 3 of the instant specification). Based on these results, the specification asserts that "a gene coding N-type calcium channel [...] showed an anti-depression response in the two depression related behavior tests" (middle at p. 7), and further, that "the inhibition of the activity of N-type calcium channel by suppressing the expression of an alpha 1B protein results in the anti-depression response, suggesting that an N-

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type calcium channel gene activity inhibitor or its product N-type calcium channel activity inhibitor might be used for the development of a depression treatment agent” (pp. 9-10).

The state of the art is exemplified by the following. Voltage-gated calcium channels are well described in the art and represent a major route of calcium translocation across the plasma membrane of excitable cells. The art teaches that N-type channels are involved in release of major neurotransmitters such as norepinephrine, acetylcholine and adenosine (Fossier et al., 1994, PNAS USA, Vol. 91, pp.4771-5, see p.4771, for example). Mynlieff et al. article (Mynlieff et al., 1994, J. Neuroscience, 14(6), pp.3628-34) discloses that on mouse motoneurons, adenosine decreases (inhibits) N-type current. Further, N-type channels are known to be involved in many important physiological functions, such as cardiac rhythm and blood pressure, for example (see Uneyama et al., 1999, Europ. J. Pharmacol., 373, pp.93-100). The art does not recognized that N-type calcium channels, including 1B N-type calcium channels are specifically associated with etiology or course of clinical depression, a psychiatric disorder.

While the skill level in the art is high, the level of predictability is low. The art teaches that most of the excitable cells comprise plurality of N-type calcium channels, and that there are many ways in which these channels are regulated. The instant specification fails to present any evidence or sound scientific reasoning to support a conclusion that N-type calcium channel is specifically associated with depression or that depression is regulated by N-type calcium channel activity. Further, the sole working examples in the specification, as originally filed, pertain to behavioral experiments performed on knockout mice, which lack 1B N-type calcium channel gene. The instant specification fails to present any explanation or reference to the art to substantiate the choice of the animal model used in the experiments, such as that the 1B

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knockout mouse is an art-recognized model, which serves as representative or predictive of clinical depression in humans. While it is not necessary that Applicant understands or discloses the mechanism by which the invention functions, in this case, in the absence of such an understanding, no extrapolation can be made of the limited results of experiments on mice lacking N-type calcium channel gene, to methods of treatment of pathological conditions, or to humans or other primates, in view of the art recognition that N-type calcium channels are involved in many different physiological functions and that N-type calcium channel are not recognized as being specifically associated with depression.

Applicant's invention is predicated on the finding that N-type calcium channel knockout mice perform differently in behavioral tests generally used to study depression. Applicant further extrapolates this result into a method for treating depression by administration of an inhibitor of N-type calcium channel. Accordingly, it would appear that Applicant provides a single finding (the finding), and then presents an invitation to experiment and determine if inhibition of N-type calcium channel has any effect on the course of clinical depression, and then to assay and discover which inhibitors are suitable as pharmaceuticals for administration to a subject suffering from depression, as well as routes and regimes of administration.

A patent is granted for a completed invention, not the general suggestion of an idea and how that idea might be developed into the claimed invention. In the decision of *Genentec, Inc. v. Novo Nordisk*, 42 USPQ 2d 100, (CAFC 1997), the court held that:

“[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable” and that “[t]ossing out the mere germ of an idea does not constitute enabling disclosure”. The court further stated that “when

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there is no disclosure of any specific starting material or of any of the conditions under which a process is to be carried out, undue experimentation is required; there is a failure to meet the enablement requirements that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art”, “[i]t is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement”.

The instant specification is not enabling because one cannot follow the guidance presented therein and practice the claimed methods without first making a substantial inventive contribution.

Double Patenting

4. Applicant is advised that should claim 1 be found allowable, claim 3 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). In the instant case, claim 3 recites that the inhibitor is a substance that acts specifically to inhibit the activity of the channel, which appears to be just a recitation of what constitutes an inhibitor without addition of any other material limitation, which would allow distinguishing the claimed subject matter of these two claims.


Conclusion

5. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Olga N. Chernyshev, Ph.D.
Primary Examiner
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October 17, 2006